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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	David B. Anderson, et al.	
Serial No.:	811,059	Group Art Unit: 125
Filed :	December 19, 1985	
For :	GROWTH PROMOTION	Examiner: F. Waddell
Docket No.:	X-5683B	

DECLARATION UNDER 37 C.F.R. 1.132

Commissioner of Patents and Trademarks

Washington, D.C. 20231

Sir:

I, David B. Anderson, hereby declare and say as follows:

I received a Bachelor of Science degree in 1966 from South Dakota University in the field of animal science. I received an M.S. degree in animal science in 1968 from the University of Wisconsin, and a Ph.D. from the same institution in 1971 in biochemistry and animal science.

From 1972 to 1975 I was chief of the Biochemistry Branch of the Aeromedical Research Laboratories of the U.S. Army. From 1975 to 1979, I was assistant professor of animal science at the University of Illinois. In 1979 I joined Eli Lilly and Company as a senior scientist in the animal nutrition research division. I was promoted to research scientist in 1983. Since 1979, I have been responsible for conducting and supervising basic and applied research for Eli Lilly and Company in the area of animal nutrition and animal growth.

I am one of the inventors named in the above-captioned patent application. I am familiar with the subject matter of that application and the invention of Claims 12, 23, 35, and 36.

I am familiar with the prior art cited in the application, and specifically with the references relied upon by the Examiner which form the basis for rejection of the claimed subject matter. I am familiar with the Dijk et al. and Mills et al. references which teach one of the compounds required to conduct the now claimed method, namely, the compound referred to within Lilly as 31537. That compound is described by Dijk et al. as a utero-spasmolytic agent, and by Mills et al. in the EPA 7205 reference as a cardiotonic agent. I am also familiar with Mills et al. U.S. Patent No. 4,391,826 which describes the use of β-phen-ethanolamines as antiobesity agents and for improving leanness in livestock animals. One of the compounds disclosed by the Mills '826 patent is known within Lilly as 79771 and is the subject of Example 11 in the Mills patent.

I have conducted or have been directly involved in a number of experiments designed to compare 31537 to 79771 in their respective ability to promote growth in animals and to improve feed efficiency and leanness. I was one of the Declarants in a Declaration submitted in the parent application that established the unexpected superiority of 31537 in its ability to promote growth and improve feed efficiency in swine when compared to 79771. I am familiar with the data that is presented in a Declaration by Dr. D. J. Jones which establishes to my satisfaction that 31537 is substantially more active than 79771 in its ability to promote growth and improve feed efficiency and leanness in swine. I have been directly involved in a comparative study carried out in steers that has established to my complete satisfaction that 31537 is far

superior to 79771 as a growth promoter and improver of feed efficiency. The experiment that was carried out in steers was conducted as follows.

A total of 54 Hereford-cross steers were employed for the study. The animals were divided into 3 groups of 18 animals each, one group serving as controls who received no drug treatment, another group of animals who received 200 mg. per head per day of 31537, and the other group of 18 animals who received 200 mg. per head per day of 79771. All animals received a normal feed ration of high moisture corn, corn silage and supplement. The 31537 and 79771 were formulated in a corn based carrier for oral administration to the animals, and the control group of animals received the same corn based carrier without the drug. All animals were fed for 28 days, at which time the study was terminated and the results calculated. The results of the study are presented in the following table.

TABLE 1

Treatment	Level (mg/head/day)	No. Animals	Start Wt.(lbs)	ADG (lbs)	ADF (lbs)	G/F
Control	0	18	1101	2.82	17.0	.163
Cmpd. 31537	200	18	1103	3.49 (23.8%)	17.0	.209 (28.2%)
Cmpd. 79771	200	18	1103	3.05 (8.2%)	16.9 (-0.6%)	.178 (9.2%)

The average daily gain (ADG) was calculated by substracting the starting weight of the animals from the finishing weight and then dividing by 28 days of treatment. The average daily feed (ADF), which is the dry matter feed intake per day, was calculated by measuring the total amount of feed consumed on a dry matter basis by each animal in a particular group and dividing that by 28 days. The feed efficiency is simply the ratio of average daily

gain to average daily feed (G/F). The data in the table establish that 31537 caused an increase of 23.8% in average daily gain compared to untreated controls. In contrast, 79771 effected only an 8.2% increase relative to untreated controls. The table additionally shows that compound 31537 effected no change in the average daily feed intake of the animals, and 79771 caused a negligible decrease in the amount of average daily feed consumed. Compound 31537 effected a 28.2% improvement in feed efficiency, whereas 79771 caused only a 9.2% improvement in feed efficiency. The data establish that 31537 is essentially three-fold more active than 79771 in its ability to improve average daily gain and feed efficiency. There is nothing in any of the prior art of record that would lead to the suggestion of this unexpected superiority.

I further declare that all statements made herein of my own knowledge are true, that all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both (18 U.S.C.1001), and may jeopardize the validity of the application or any patent issuing thereon.

David B. Anderson

10/17/86
Date